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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,346	01/20/2006	Jane Hirsh	CPX-015.01	1923

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,346	HIRSH ET AL.	
	Examiner	Art Unit	
	MINA HAGHIGHATIAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/13/09 & 05/19/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments, Remarks and an IDS filed on 04/13/09 and a second IDS filed on 05/19/09. Claims 1 and 12 have been amended, and no claims cancelled or added. Accordingly, claims **1 and 3-13** remain pending.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Note: claims appear to contain certain typographical errors such as the name of active agents (e.g. alclometasone, beclamethasone, etc). Corrections are required.

Claim Rejections - 35 USC § 112

Claims 1 and 3-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendments of 04/13/09, added the limitation of "the oil phase of the emulsion is about 0.5% to about 3.0% by weight of the emulsion". The specification does not provide adequate support for the added limitation. The range of 0.5 to 3.0% for the oil phase is no where to be found in the specification.

The total amounts of the components considered components of the oil phase in Examples 1-3 can support a range of 0.8 to 6.0%. However the recited range is considered new matter. Applicants have failed to identify where they think they have support for the added limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20060140984) in view of Davis (5,143,717) and in further view of Sachetto (WO 9603115A1).

Tamarkin et al disclose an alcohol-free cosmetic or pharmaceutical foam carrier comprising water, a hydrophobic solvent, a foam adjuvant agent, a surface-active agent

and a water gelling agent (see abstract). The said alcohol-free foamable carriers, when placed in an aerosol container and combined with a liquefied gas propellant, create an oil in water emulsion, which upon release from the aerosol container, provides a therapeutically beneficial foam product (see [0025]). The foam carrier includes active agents, both water soluble and oil soluble (see [0063]). The foam is easily spreadable, allowing treatment of large areas as the arms, back, legs and breast (see [0064]). Examples of suitable propellants include volatile hydrocarbons such as butane and fluorocarbon gases (see [0115]). Examples of suitable active agents include antibiotics, antifungals, anesthetics, anti-inflammatory agents, corticosteroids, etc (see [0226]). Anti-inflammatory agents include clobetasone, betamethasone, diclofenac, ketorolac, ibuprofen (see [0245] and [0252]-[0257]). Antifungals include fluconazole, ketoconazole, clotrimazole, etc (see [0234] to [0237]). Antibiotics include penicillins, macrolides, beta-lactams, etc ([0229]). Anesthetics include lidocaine, bupivacaine, dibucaine, etc (see [0264]). Example 8 discloses a foam formulation comprising antibacterials in an amount of about 2%. Example 9 discloses a foam formulation comprising 1-2% antifungals. Example 10 discloses foam formulations comprising 0.05 to 1% of corticosteroid anti-inflammatory agents. Example 18 discloses a foam formulation comprising 4% lidocaine. Example 1 discloses a method of preparing the foam formulations.

Tamarkin et al lacks disclosure on the oil phase being solid or semi-solid at room temperature. This deficiency has been remedied by Davis. Tamarkin et al also lacks specific disclosure on hydrofluroalkanes as propellants. However this deficiency has been cured by Schetto.

Davis teaches burn foam and delivery system. The said foam is an antibiotic formulation useful in the treatment of burns and abrasions and adapted for topical application as a clinically water soluble foam (see abstract). The process steps in preparation of the said foam formulation include **heating and melting** the white petrolatum and other ingredients until all dints are melted and thoroughly to form the **oil phase** of the emulsion (see col. 4, lines 26-40). In a table on columns 5-6, multiple formulations have been exemplified with the concentration of each component. Examples VI-XV appear to contain an oil phase that is less than 3% (white petrolatum at 2.45%). The formulations also comprise a mixture of propane and isobutene as the propellant portion.

Sachetto teaches aqueous foamable compositions comprising active agents surfactants and foaming agents. The foaming agent is preferably a so-called liquefied gas, including propane, butane, isobutene or environmentally friendly propellants such as HFA 134a and HFA 227 (see page 4 and Table 1). Such foamable formulations have been exemplified in examples 1-21. Tables such as Table IV, discloses ingredients used in examples 10-14, which include a foaming agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tamarkin et al, Davis and Sachetto on forming foam compositions with a reasonable expectation of successfully preparing stable foam formulations for treating various disorders topically. Tamarkin et

al teach an alcohol-free foam composition where the oil phase is liquid at room temperature and Davis teaches a foam formulation where the oil phase is solid at room temperature. Tamarkin discloses that the foam formulations comprise a propellant and Sachetto discloses that propellants such as HFAs are suitable and environmentally friendly propellants and are used in foam formulations. One of ordinary skill in the art could have selected the solid phase of Davis over the liquid phase of Tamarkin et al with predictable results. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 1 and 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20060233721) in view of Quigley, Jr. et al (6,075,056) and in further view of Sachetto (WO 9603115A1).

Tamarkin et al teach foamable composition for administration to the skin, body surface, body cavity or mucosal surface, e.g. the mucosa of the nose, mouth, eye, ear, respiratory system, etc. The foamable oil in water emulsion composition includes: an oil globule system, selected from the group consisting of oil bodies; and sub-micron oil globules, about 0.1% to about 5% by weight of an agent, selected from the group consisting of a surface-active agent, having an HLB value between 9 and 16 and a

polymeric agent and a liquefied or compressed gas propellant at a concentration of about 3% to about 25% by weight of the total composition, water and optional ingredients are added to complete the total mass of 100% (see abstract and [0012]). The said foamable composition further includes at least one therapeutic agent such as an anti-inflammatory agent, antifungal or antibacterial, anesthetics etc (see [0026]). A polar solvent such as polyols ([0064]). The foamable compositions may be substantially alcohol-free, i.e. **free of short chain alcohols**, having up to 5 carbon atoms in their carbon chain skeleton (see [0066]). The formulations may be in an oil-in-water emulsion ([0080]). Suitable propellants include volatile hydrocarbons and fluorocarbon gases ([0098]). Claim 1 is drawn to a foamable oil in water emulsion composition comprising an oil globule, a non-ionic surface active agent, water and a liquefied propellant.

Tamarkin et al does not disclose an oil phase wherein the emulsion is a solid or semi-solid at room temperature. This deficiency has been remedied by Quigley et al. Tamarkin et al also lacks specific disclosure on hydrofluroalkanes as propellants. However this deficiency has been cured by Schetto.

Quigley, Jr. et al teach stable topical formulations comprising an antifungal agent and an anti-inflammatory steroid useful for treating fungal diseases and their related inflammation (see abstract). The topical formulations may be in the form of foam, cream, lotion, solution, etc (see col. 7, lines 31-34). To prepare the oil phase of the said topical formulations, it is said that the drugs are dissolved in the oil phase consisting of melted oil-soluble components of the formulation prior to addition of this phase to the

aqueous phase (see col. 8, line 65 to col. 9, line 3). Other examples disclose similar process steps. Quigley et al also discloses that "white petrolatum is an emollient cream base and can be replaced by mineral oil" (see col. 8, lines 50-51). The cream formulations in Tables A and B show formulations comprising less than 10% oil phase (from 2 to 10% glycerin in Table A and from 1-20% white petrolatum in Table B).

Sachetto teaches aqueous foamable compositions comprising active agents surfactants and foaming agents. The foaming agent is preferably a so-called liquefied gas, including propane, butane, isobutene or environmentally friendly propellants such as HFA 134a and HFA 227 (see page 4 and Table 1). Such foamable formulations have been exemplified in examples 1-21. Tables such as Table IV, discloses ingredients used in examples 10-14, which include a foaming agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tamarkin et al, Quigley, Jr. et al and Sachetto on stable topical formulations comprising active agents such as antifungal agents and anti-inflammatory steroids useful for treating various diseases with a reasonable expectation of successfully preparing stable and effective topical foam preparations. Tamarkin et al teach foam formulations wherein the oil phase is a liquid at room temperature and the formulations are substantially free of lower alcohols. Quigley teaches topical formulations that can be in the form of foam and wherein the oil phase of the oil-in-water emulsion is soli or semi-solid at room temperature and is mixed with

the aqueous phase after being melted. Tamarkin discloses that the foam formulations comprise a propellant and Sachetto discloses that propellants such as HFAs are suitable and environmentally friendly propellants and are used in foam formulations. One of ordinary skill in the art would have been able to select the solid oil phase of Quigley and the substantially free of alcohols foam formulation of Tamarkin et al with expected results. That is, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Additionally, the claims would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Response to Arguments

Applicant's arguments filed 04/13/09 have been fully considered but they are not persuasive.

Applicant's arguments with regard to the rejection of claims under obviousness over '388 in view of '331; the rejection of claims over '388 in view of '331 and further in view of US '182; and the rejection of claims over WO 9603115 in view of '717 are persuasive and the said rejections have been withdrawn.

In the remarks, Applicant repeatedly states that the two Tamarkin et al references (US 20060140984 and US 20060233721) do not qualify as prior art under 35 USC 102(e) against the instant claims with respect to hydrofluoroalkane propellants. This is correct, however the Examiner did not rely on the said references for recitation of hydrofluoroalkane propellants. The rejections make it clear that the said references do not teach hydrofluoroalkane propellants. The deficiency was cured by WO 9603115.

Applicant argues that WO 9603115 is directed towards foamable aqueous compositions, whereas, the current claims are directed towards oil-in-water emulsions. Applicant states the difference between solubility of HFAs in water and in an oil-in-water emulsion and states that the solubility of HFA propellants in oil-in-water emulsion would arguably be much higher. Applicant believes "that one of ordinary skill in the art would not have considered HFA propellants to be among the finite number of suitable alternatives that would have been obvious to try". This is not persuasive. Since the CFCs have been banned from use for their environmental effect, HFAs have been the most common and natural replacement in most cases. Examiner also disagrees with the Applicant's assertion that there would be finite number of suitable alternatives. As seen in the references of record, the choices are between hydrocarbon propellants, gases and HFAs. Hydrocarbons and gases have their shortcomings such as flammability, stability, etc. Thus, HFAs appear to be the most reasonable choice and well known to those in the field.

In response to Applicant's arguments that suitable propellants for aqueous formulations of WO 9603115 is not persuasive because the solubility of the HFAs does

not affect the formulation. In an oil-in-water emulsion the outer phase is water thus the aqueous formulation and the oil-in-water emulsion would have the same medium for the propellant. Also, a water-soluble propellant such as HFA would be soluble in water and would be dispersed in the oil phase. Thus a suitable propellant for an aqueous formulation would also be suitable for an oil-in-water emulsion.

Applicant also argues that the references do not teach a formulation where the oil phase is in the amount of 0.5 to 3.0% by weight. This is not persuasive because Davis teaches formulations that contain less than 3% oil phase (see Examples VI-XV). Also Quigley et al discloses formulations that have 0-10% white petrolatum. Furthermore, according to MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." ***In re Aller***, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Claims 1 and 3-13 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
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Art Unit 1616